

**PATENT**  
**CL-213**

*Heidi S.  
Giblin  
1/7/94*

I do hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail on the date indicated below and is addressed to the Commissioner of Patents and Trademarks, Washington, D. C. 20231.

*Marilyn Hadfield*  
Marilyn Hadfield

Date

*Jan. 7, 1994*

*FAX COPY*  
*RECEIVED*

*JAN 07 1994*

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Petra Boyle )  
                  Gayle D. Wetzel )  
                  Kenneth J. Lembach )  
                                       ) SUPPLEMENTAL AMENDMENT  
Serial No.: 08/026,957      )  
                                       ) EXAMINER: R.D. BUDDENS  
                                       )  
Filed: March 5, 1993        )  
                                       ) ART UNIT: 1806  
Title: HUMAN ANTI-TNF )  
                                       )  
                                       )  
                                       )

Commissioner of Patents and Trademarks  
Washington, D.C. 20231

Sir:

Shortly after filing an Amendment on December 22, 1993, the Applicants noted a typographical error on page 4. Please enter the enclosed corrected copy of page 4 so that the revised sentence makes sense.

Respectfully submitted,

Dated: January 7, 1994

*James A. Giblin*  
James A. Giblin  
Attorney for Applicants  
Reg. No. 25,772  
Miles Inc.  
P. O. Box 1986  
4th & Parker Streets  
Berkeley, CA 94701  
(510) 420-5511

PATENT  
CL-213Re 35 USC 101 and 112 (Utility and Enablement):

The Specification and claims 1 - 10 and 12 - 14 were rejected under 35 USC 112 first paragraph on the grounds that the specification does not provide an enabling disclosure in that there is no indication of patentable utility for the claimed antibodies. Reconsideration is again requested. It is submitted that one skilled in the art would readily recognize the value of any monoclonal antibody directed to a specific substance such as TNF. The antibody has been shown to be able to bind to TNF. It is submitted that a demonstration of a mere binding of human anti-TNF alpha is sufficient demonstration of utility under the patent statute. At the very least, such binding would be useful in simple applications where one would want to use an antibody known to bind selectively with TNF (e.g., an immunoassay or purification step). See, for example, Table 1 on page 13 where the Applicants have demonstrated how far <sup>ANTI-  
ANTIBODIES</sup> <sub>TNF</sub> can be diluted while still showing binding to ~~the cited human anti TNF alpha antibodies.~~ Therefore, reconsideration of the basis for rejection is respectfully requested.

Re 35 USC 112, first paragraph (the Cell Line Deposits):

Three of the cell lines used to express the human monoclonal antibodies of the invention have been deposited with ATCC under the Budapest Treaty, as shown on the enclosed deposit notice copies. The undersigned attorney of record hereby certifies that